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Abstract: Despite the failure of the international extracranial-intracranial (EC-IC) bypass study in showing the benefit of bypass procedure for prevention of stroke recurrence, it has been regarded to be beneficial in a subgroup of well-selected patients with haemodynamic impairment. This report includes the EC-IC bypass experience of a single centre over a period of 14 years. All consecutive 72 patients with atherosclerotic occlusive cerebrovascular lesions associated with haemodynamic compromise treated by EC-IC bypass surgery were retrospectively reviewed. Pre-operatively, 61% of patients presented with minor stroke and the remaining 39% with recurrent transient ischemic attacks (TIAs) despite maximal medical therapy. Angiography revealed a unilateral internal carotid artery (ICA) stenosis/occlusion in 79%, bilateral ICA stenosis/occlusion in 15%, MCA stenosis/occlusion in 3% and other multiple vessel stenosis/occlusion in 3% of the cases. H(2)(15)O positron emission tomography (PET) or 99mTc-HMPAO SPECT with acetazolamide challenge was performed for haemodynamic evaluation of the cerebral blood flow (CBF). All the patients had impaired haemodynamics pre-operatively in terms of reduced regional cerebrovascular reserve capacity and rCBF. Standard STA-MCA bypass procedure was performed in all patients. A total of 68 patients with 82 bypasses were reviewed with a mean follow-up period of 34 months. Stroke recurrence took place in 10 patients (15%) resulting in an annual stroke risk of 5%. Improved cerebral haemodynamics was documented in 81% of revascularised hemispheres. Patients with unchanged or worse haemodynamic parameters had significantly more post-operative TIAs or strokes when compared to those with improved perfusion reserves (30% vs.5% of patients, p<0.05). In conclusion, EC-IC bypass procedure in selected patients with occlusive cerebrovascular lesions associated with haemodynamic impairment has revealed to be effective for prevention of further cerebral ischemia, when compared with a stroke risk rate of 15% reported to date in patients only under antiplatelet agents or anticoagulant therapy.

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Extracranial-intracranial Bypass in Atherosclerotic Cerebrovascular Disease: Report of a Single Centre Experience.

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Abstract

Despite the negative results of the international EC-IC bypass study, well-selected patients with haemodynamic impairment might benefit from the bypass procedure in terms of stroke prevention. This report is about a single centre experience in EC-IC bypass procedure. All patients with atherosclerotic occlusive cerebrovascular diseases treated by EC-IC bypass surgery were retrospectively reviewed. Preoperatively, 61% of patients presented with minor stroke and the remaining 39% with recurrent TIAs despite maximal medical therapy. Angiography revealed a unilateral ICA stenosis/occlusion in 79%, bilateral ICA stenosis/occlusion in 15%, MCA stenosis/occlusion in 3% and other multiple vessel stenosis/occlusion in 3% of cases. $H_2{}^{15}O$ PET or 99mTc-HMPAO SPECT with acetazolamide challenge was performed for haemodynamic evaluation. All patients had impaired haemodynamics preoperatively in terms of reduced rCVR and rCBF. Standard STA-MCA bypass was performed in all patients. A total of 68 patients with 82 bypasses were reviewed with a mean follow-up of 34 month. Overall postoperative stroke occurred in 10 patients (15%) resulting in an annual stroke risk of 5%. Improved cerebral haemodynamics was documented in 81% of revascularized hemispheres. Patients with unchanged or worse haemodynamic parameters had significant more postoperative TIAs or stroke ($P < 0.05$). In conclusion, EC-IC bypass procedure in selected patients with occlusive cerebrovascular disease and haemodynamic impairment is useful. Compared to earlier described stroke risk in natural history of patients with compromised haemodynamics, the current results indicate a risk reduction by EC-IC bypass surgery.

Key-words: EC-IC bypass, carotid occlusion, PET, acetazolamide, stroke, cerebral revascularization

Introduction

The extracranial-intracranial (EC-IC) bypass was widely used to treat occlusive cerebrovascular disease that was not amenable to carotid endarterectomy since its introduction in 1967 by Yasargil and Donaghy.[1-3] It was the international randomized study of EC-IC bypass whose final results in 1985 called the role of the procedure in prevention of further recurrent stroke into question. In the latter study, bypass surgery failed to be effective in preventing cerebral ischemia, with surgical patients having strokes earlier and more frequently than patients receiving best medical treatment.[4] The international EC-IC bypass study was widely accepted, but not without critic.[5, 6] The absence of documented haemodynamic status was one the major flaws in this study.[7] Despite the failing of the international randomized EC-IC bypass study, some neurosurgeons continued to use the EC-IC bypass technique in carefully selected cases with primary occlusive cerebrovascular disease.[8-13] The fact that a certain subgroup of patients with occlusive cerebrovascular disease may benefit from bypass procedure in terms of stroke prevention is still controversial.[7, 14, 15] The aim of this study was to report about the experience and results on EC-IC bypass in patients with occlusive cerebrovascular disease at the Department of Neurosurgery, University Hospital of Zurich, Switzerland.

Clinical material and methods

We retrospectively analyzed all patients with atherosclerotic single or multiple vessel occlusive diseases treated with EC-IC bypass operation between 1993 and

2007 at the Department of Neurosurgery, University Hospital of Zurich, Switzerland. All patients suffered from symptomatic occlusive disease refractory to medical treatment. Revascularization procedures for the posterior circulation were not analyzed in the current study. Further, patients who underwent EC-IC bypass procedure due to therapeutic occlusion of intracranial arteries for unclippable aneurysm or cranial base neoplasm and patients with Moyamoya-angiopahty have been excluded from this study. All patients underwent conventional 6-vessel angiography for presurgical diagnostics (Figure 1). For evaluation of regional cerebral blood flow (rCBF) and regional cerebrovascular reserve capacity (rCVR), $H_2{}^{15}O$ positron emission tomography (PET) or 99mTc hexamethylpropylene amine oxime single photon emission computed tomography (SPECT) examinations using acetazolamide (Diamox®) loading was performed preoperatively (Figure 2).[16] Candidates for surgery had to fulfil all three criteria as shown in Table I. Revascularization surgery was performed between 3 weeks and 3 months after a minor stroke, since surgery before 3 weeks after a stroke has been reported to have higher risk of bleeding on revascularization and the period 3-6 months after a stroke is considered to be a frequent stroke recurrence period.[17] The number and localization of bypasses depended on the result of the PET or SPECT examination and angiography. Bypass surgery was performed after the method described in detail elsewhere.[3] All patients received 300 mg acetylsalicylic acid (Aspirin cardio®) per day postoperatively.

EC-IC bypass procedure: Under general anaesthesia, the head was fixed with Mayfield apparatus so that the plane of the squama temporalis came on the top as horizontal plane. After shaving, the running course of the parietal branch and/or frontal branch of the superficial temporal artery (STA) was identified under the guidance of Doppler sonography. The STA was dissected in the skin flap after reflection of a question mark incision, or it was dissected under the linear incision, in a length of 8-10 cm. The arterial dissection was done including periadventitial tissues. After cutting the temporal musculature along its muscle fiber, the squama temporalis was exposed. The centre of the craniotomy was placed at the point of ca. 6 cm cranial to the porus acusticus externus. This point is supposed to correspond with the end of the Sylvian fissure, from which branches of the middle cerebral artery (MCA) of ca. 1mm in diameter emerge onto the cortical surface. One burr hole was placed just caudal to the sutura squamosa and a small bone flap of around 3 cm diameter was sawed out towards cranial. After the opening of the dura and arachnoidea, one of the cortical arteries of around 1 mm in diameter was dissected in a length of 1cm coagulating and cutting several tiny branches of the artery. A rubber dam was inserted between the cortical surface and the dissected segment of the cortical artery for the isolation of the latter. The segment was closed with mini temporary clips and an elliptical arteriotomy in a length of 1.0-1.5 mm was performed. The cut end of the already dissected STA was brought on to the recipient artery. After its temporary proximal occlusion and irrigation of the lumen with heparin solution, the periadventitia was peeled off at its distal end. The end was cut so that the diagonal diameter corresponded with the opening of the recipient artery. An end-to-side anastomosis was accomplished with 8 interrupted sutures with 10-0 monofilament nylon thread. After completion of the anastomosis, the temporary clips and rubber dam were removed, and the patency was checked by micro-Doppler. After application of cellulose-gauze (Tabotamp®) around the suture line, the dura was approximated and closed. Compression or stenosis of the donor STA was avoided at the time of bone replacement, muscle-fascia and skin closure.

In general, patients were followed-up after 3 month with an angiography and Doppler-ultrasound for bypass patency and then in a yearly basis in the outpatient clinic with neurological examination and Doppler ultrasound. The majority of patients had a postoperative PET or SPECT to document changes in cerebral haemodynamics after 3-6 month. Clinical outcome was assessed by an outcome scale as shown in Table II. Data are given as mean ± standard deviation (SD). Numeric variables were analyzed by the independent t-test and nominal variables by the Fisher's exact test. A *P*-value < 0.05 was regarded as statistically significant.

Results

A total of 86 STA-MCA bypass-procedures in 84 surgical sessions were performed in 72 patients. The female to male ratio was 1:1.8 and the mean age of all patients was 63 ± 10 years (range 44-82 years). Preoperatively, 44 patients (61%) presented with minor stroke and the remaining 28 (39%) patients presented with recurrent transient ischemic attacks (TIAs). Angiographic lesions for which the indication for surgery was made were as following: unilateral internal carotid artery (ICA) occlusion in 72%, bilateral ICA stenosis or occlusion in 15%, unilateral ICA stenosis in 7%, unilateral MCA occlusion or stenosis in 3% and other multiple bilateral stenosis/occlusion in 3% of cases. Patient's characteristics are shown in Table III. Preoperative PET imaging was done in 48 patients and SPECT in the remaining 24 patients for haemodynamic evaluation. All patients showed haemodynamic impairment in terms of reduced rCBF and rCVR. Unilateral bypass procedure was performed in 58 patients, in one patient two STA-MCA bypasses were performed for one hemisphere (using as well the anterior as the parietal branch of the STA), in another patient bilateral bypass procedure was performed in one surgical session, and the remaining 12 patients had bilateral bypass procedures with one surgical session per side. In case of bilateral bypass procedure, the "worse" hemisphere based on the clinical and radiological presentation was done first. Postoperatively 68 patients (100%) were followed up for a mean of 34 months (range 3-165 months) and 4 patients were lost for follow-up. Overall major ipsilateral stroke occurred in 6 patients (9%) within the follow-up period, 4 (6%) of them occurred within 3-6 month after surgery. One patient with previously undetected patent foramen ovale (PFO) developed severe pulmonary embolism and paradox embolism leading to an ipsilateral stroke. Another patient with known chronic atrial fibrillation suffered from a traumatic brain injury later on, leading to a discontinuation of the coumarine medication. Thereafter the patient suffered from an ipsilateral stroke, most probably due to cardioembolic stroke. In further 2 patients, major stoke occurred few days after discontinuation of the Aspirin medication. In both patients, medication was discontinued for elective general surgical procedures: In one patient for a lung biopsy and in the other for a laparoscopic cholecystectomy. Ipsilateral minor stroke occurred in 4 patients (6%) within the follow-up period, all within 3-6 months after surgery. Recurrent TIAs occurred in 2 patients (3%). Concerning the outcome, 52 patients (77%) had a good outcome, 6 patients (9%) had a fair outcome, 5 patients (7%) had worse outcome and the remaining 5 patients (7%) were identified as dead. All patients with worse outcome had a major stroke postoperatively. Death by stroke occurred in one patient. The causes of death in the remaining 4 patients were as following: 1) Postoperative myocardial infarction 2) Postoperative intracerebral haemorrhage due to a hypertensive crisis 3) Fatal complication of a contralateral carotid endarterectomy weeks later on 4) Renal failure months later on. Age, gender or type of preoperative ischemic event was not associated with adverse outcome (Table IV). The postoperative patency was clearly verified in 65 bypasses (81%) (Figure 1), 2 bypasses (3%) were not patent and in the remaining 13 bypasses (15%), patency could not be clearly established and were classified as questionable patent. Patients with not patent or questionable patent bypasses had more stroke or recurrent TIAs, however without statistical significance (*P* = 0.15 Fisher's exact test). Bypass patency was documented up to 165 month after surgery. Postoperative haemodynamic evaluation was performed in 33 patients with 39 revascularized hemispheres by PET and in 13 patients with 14 hemispheres by SPECT (Figure 2).

Cerebral haemodynamics were improved in 43 (81%) hemispheres and unchanged or worse in 10 (19%) hemispheres. Patients with unchanged or worse cerebral haemodynamics had significantly more often postoperative stroke or recurrent TIAs (P = 0.04 Fisher's exact test).

Discussion

In the current retrospective analysis of prospectively collected data, patients with reduced cerebral haemodynamics in terms of reduced rCVR and rCBF had an overall (i.e. minor and major) stroke risk of 15% during the follow-up period, resulting in an annual risk of 5% per year. The overall mortality was 7%. Death by stroke occurred in one patient (<2%). The major flaws of the present study are certainly its retrospective nature and the lack of a control group. Further, postoperative haemodynamic evaluation was available in a majority of patients but not in all.

Reviewing the existing literature, patients with compromised cerebral haemodynamics seem to have a higher risk of subsequent stroke when treated medically.[18-21] Assessment of cerebral haemodynamics can be performed by a variety of different methods with different protocols. The quality of evidence concerning the stroke prediction is variable. Among them, measurement of oxygen extraction fraction (OEF) by PET and CVR assessment using acetazolamide administration by PET or SPECT, are most frequently reported and probably most accurate. Klijn et al. reported, from a review of the literature, that patients with impaired haemodynamics of any severity have a combined annual risk of ipsilateral stroke of 10%, and patients with severely impaired haemodynamics have an annual risk of 31%.[20] More recent studies from Japan revealed an annual ispilateral stroke risk of 17% and 24% in patients with decreased rCVR.[18, 21] Although a direct comparison with the current study is difficult due to methodological reasons, the current results indicate a beneficial effect of the bypass procedure for patients with haemodynamic impairment in terms of stroke prevention by improved cerebral haemodynamics in concordance with previous reports.[13, 14, 22-25] One has to consider the racial differences in the distribution of steno-occlusive lesions, which might present with different stroke risk and also different risk-reduction by EC-IC bypass procedure.[26, 27] It is noteworthy that in the international EC-IC bypass study a Japanese-Asian subgroup mainly consisting of MCA occlusive lesions showed less incidence of stroke recurrence in the surgical group though of no decisive statistical significance.[28] In the present study, the patient population consisted of manly Caucasians with ICA lesions (Table III). Bilateral lesions with correlating clinical and haemodynamic features were present in 13 patients (18%). Further, in up to 1/3 of 57 patients (79%) with unilateral steno-occlusive lesions of the ICA had at least one additional stenosis or hypoplasia of the contralateral ICA or posterior circulation vessels. In these patients, the additional lesion did neither cause correlating symptoms nor haemodynamic impairment per se. However it can be assumed, that the additional lesions contributed to the territorial haemodynamic impairment of the main steno-occlusive vessel in terms of poor collateralisation.

In the international EC-IC bypass study, the aspect of haemodynamic impairment has not been considered, as the methodology was immature and also not prevalent. Until today no randomized trial has been carried out to proof the superiority of bypass surgery in patients with compromised haemodynamics in terms of stroke prevention. To address this question, two randomized controlled clinical trials of EC-IC bypass in patients with atherosclerotic carotid artery occlusion using haemodynamic criteria for patient selection are in progress: The Japanese EC-IC Bypass Trial (JET-Study) has completed its enrolment (206 patients in 29 centres). Patients in the surgical group showed a statistically significant decrease in stroke occurrence.[29] The Carotid Occlusion Surgery Study (COSS) is currently enrolling patients in North America. Patients with unilateral internal carotid artery occlusion who have had ipsilateral hemispheric symptoms within 120 days are eligible to undergo PET measurements to determine if they qualify (http://www.cosstrial.org).[7] These studies might definitively confirm that the conclusions of the international EC-IC bypass trial may not be applicable to the subset of patients with impaired haemodynamics.

"Cardioembolism" is defined as one of the exclusion criteria in the JET-Study.[30] For COSS, "known heart disease likely to cause cerebral ischemia" are listed as exclusion criteria. However atrial fibrillation, PFO and atrial septal aneurysm are per se not listed as exclusion criteria (http://www.cosstrial.org).[7] In the present case series each one patient had adverse outcome by stoke due to a PFO and atrial fibrillation. In case patients have potential cardio-embolic risks beside cerebral haemodynamic impairment, the indication of EC-IC bypass should be considered carefully since risk reduction for subsequent stroke might be lower.

In two patients major ipsilateral stoke occurred after discontinuation of Aspirin for elective surgical procedures, a lung biopsy and a laparoscopic cholecystectomy. Since withdrawal of Aspirin medication is associated with an estimated risk of 10% for all vascular events, the current recommendation is to maintain Aspirin if possible throughout the perioperative period.[31] Based on the present results, Aspirin should not be stopped for elective surgery in patients with history of EC-IC bypass, whenever possible.

Because EC-IC bypass is a surgically challenging procedure, the average cumulative experience contributes to outcome over time. This surgical procedure is reported to have a particularly steep learning curve as documented by Sundt et al..[32] According to their experience, up to 20 bypass procedures were mandatory to reach a constant patency rate over 90%. In a population-based study, Amin-Hajani et al. found that 1/3 of bypasses in the US were performed in “lower-volume” centres with less than one operation yearly.[33] The more, an increased risk of adverse outcome at discharge from a “lower-volume” centre after any EC-IC bypass procedure in the US was found. Therefore he concluded that due to the low caseloads, referral of patients who require EC-IC bypass to a small number of “high-volume” centres might improve outcome and help to maintain the technical surgical skills. At the Department of Neurosurgery, University Hospital Zurich, a total of 327 EC-IC bypass procedures in 265 patients were performed in a 14 years period, about each 1/3 for atherosclerotic occlusive disease, Moyamoya-angiopathy and therapeutic occlusion of intracranial arteries for unclippable aneurysm or cranial base neoplasm. It can be assumed, that in this time period, the caseload was one of the highest in Switzerland. Nevertheless complications and adverse outcome were present in the current case series. Since patients with atherosclerotic occlusive disease are often polymorbid, experienced overall perioperative patient management is mandatory beside the technical surgical skills for bypass procedure. Therefore “pooling” of EC-IC bypass procedures in determined centres is of interest to gain and maintain not only surgical skills but also overall perioperative management.

Conclusions

The results of this single centre study show the feasibility of EC-IC bypass procedure in selected patients with occlusive cerebrovascular disease and haemodynamic impairment in terms of reduced rCVR and rCBF. The overall annual risk for ipsilateral stroke was 5% per year. Compared to previously described stroke risk in natural history of patients with compromised haemodynamics, the current results indicate a risk reduction by EC-IC bypass surgery. In patients with EC-IC bypass, a maximum of effort is needed to avoid any perioperative cardio-vascular complications.

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Figure legends

Figure 1. Preoperative Angiography, anterior-posterior (A) and oblique view (B), shows a complete occlusion of the right ICA (arrow). Postoperative angiography, antererior-posterior view (A) and lateral view (B), shows a filling of the distal braches of right MCA (arrowhead) by a patent bypass (arrow) via the right STA.

Figure 2. Upper 2 rows show preoperative $H_2{}^{15}O$ PET images with a decreased baseline CBF and decreased reactivity on acetazolamide (Diamox®) in the right hemisphere. The lower two rows show postoperative $H_2{}^{15}O$ PET images with an increase as well in baseline CBF as in acetazolamide-reactivity in the parieto-temporal region of the right hemisphere.

Table I

Indication criteria of the STA-MCA bypass

1.	Clinical	Recurrent TIAs or minor stroke with no or minor neurological deficits
2.	Angiography	a) MCA-M1 occlusion or stenosis (> 50%) b) ICA occlusion c) ICA stenosis (> 50%) above the mandibulomastoid line
3.	PET/SPECT	Haemodynamic compromise with reduced rCVR and reduced baseline rCBF

TIA: transient ischemic attack, MCA: middle cerebral artery, ICA: internal carotid artery, rCVR: regional cerebrovascular reserve capacity, rCBF: regional cerebral blood flow.

Table II

Outcome Scale

Good	-	neither major nor minor strokes occur
	-	no worsening or improvement of any preoperative deficit
Fair	-	further minor stroke or recurrent TIAs occur
	-	no worsening of any preoperative deficit
Worse	-	further major stroke occur
	-	worsening of any preoperative neurological deficit
Dead	-	patient died due to perioperative complications or due to other reasons

Table III

Patient's characteristics

Age (years ± SD)	63	± 10
Gender (n)		
Male	46	(64%)
Female	26	(36%)
Preoperative symptom (n (%))		
TIAs	28	(39%)
Minor stroke	44	(61%)
Most distal angiographic lesion* (n (%))		
ICA occlusion	52	(72%)
ICA stenosis	5	(7%)
MCA stenosis/occlusion	2	(3%)
Bilateral ICA stenosis/occlusion	11	(15%)
Bilateral MCA stenosis/occlusion	1	(3%)
ICA occlusion, contralateral MCA stenosis	1	

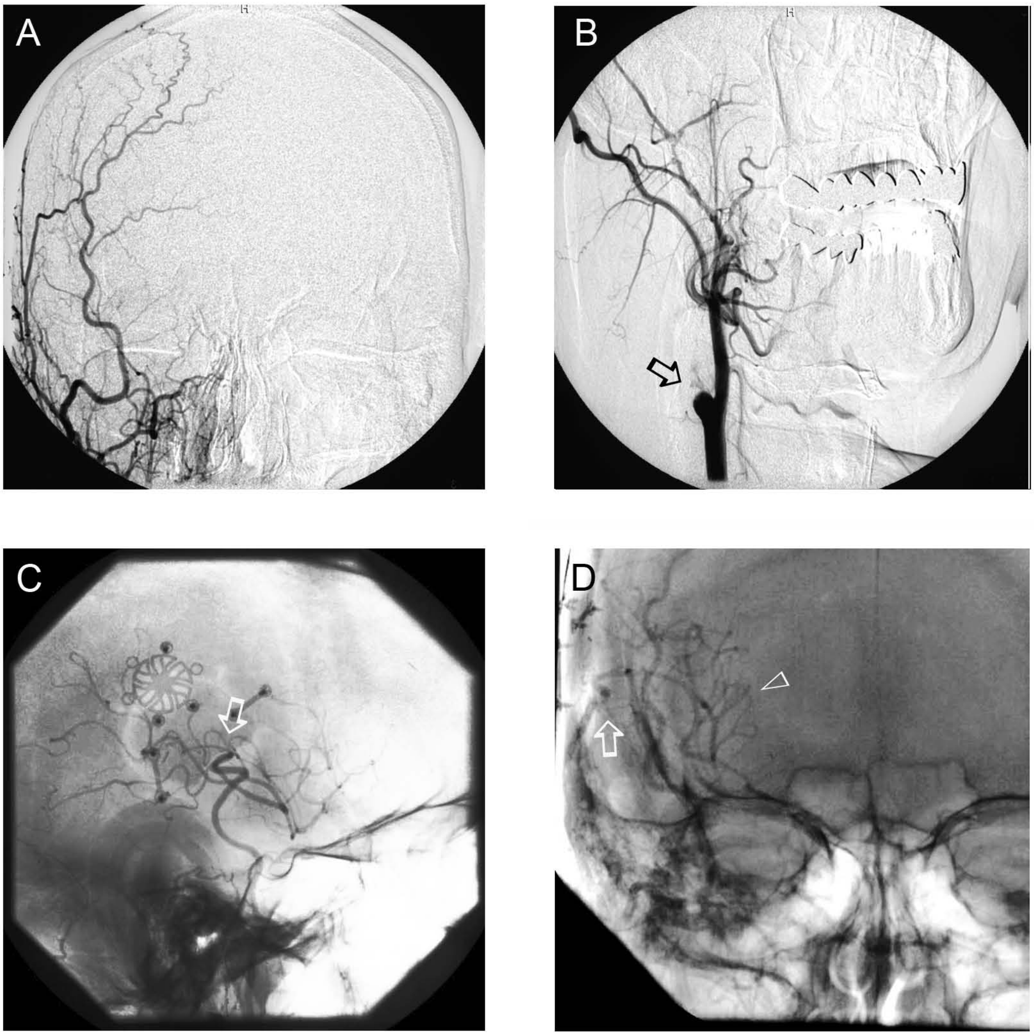
SD: standard deviaton, TIA: transient ischemic attack, ICA: internal carotid artery, MCA: middle cerebral artery, *refers to the most distal angiographic lesion for which the indication for surgery was given.

Table IV

Dichotomized outcome in relation to baseline characteristics

	Outcome		
	good/fair (n = 58)		worse/dead (n = 10)
Age (years ± SD)	62.3 ± 9.2	*ns**	63.2 ± 10.9
Gender (female:male)	1:1.42	*ns***	1:9
Preoperative symptom (minor stroke:TIAs)	1:1.32	*ns***	1:2.3

SD indicates standard deviation; TIA, transient ischemic attack; ns, statistically not significant; *independent t-test; **Fisher's exact test.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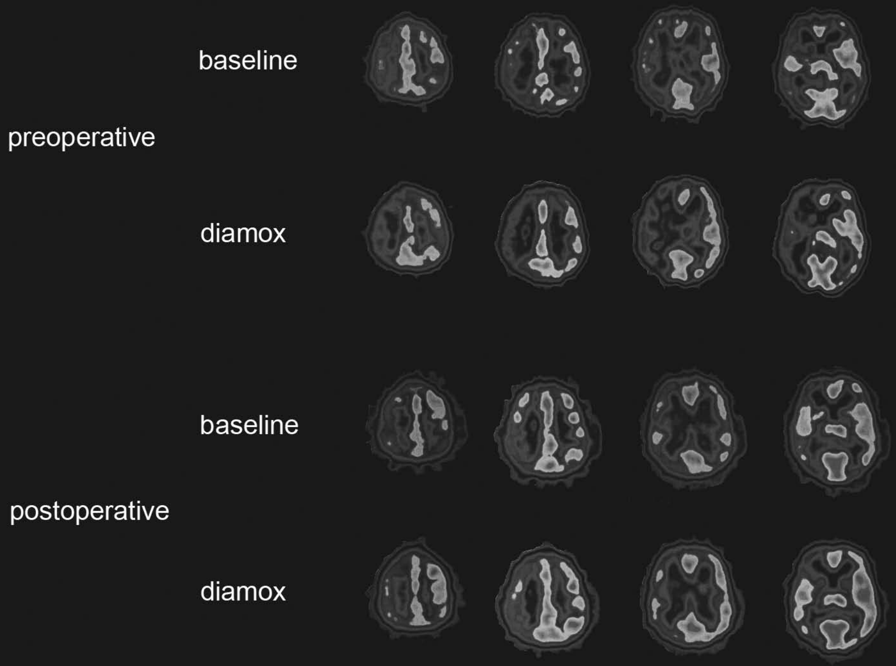
preoperative
baseline
diamox
postoperative
baseline
diamox